

July 9, 2015

The Honorable John Boehner
Speaker of the House
U.S. House of Representatives
H-232, U.S. Capitol
Washington, D.C. 20510

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
H-204, U.S. Capitol
Washington, D.C. 20510

Dear Speaker Boehner and Minority Leader Pelosi:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to offer our strong support for H.R. 6, the 21st Century Cures Act, and urge the House of Representatives to pass this important legislation.

We applaud Chairman Fred Upton (R-MI), Ranking Member Frank Pallone (D-NJ) and Congresswoman Diana DeGette's (D-CO) efforts on H.R. 6., which takes important steps toward placing patients at the center of the drug development process, and we believe will help spur the development of therapies for the most prevalent conditions, as well as encourage development of treatments focused on rare conditions and other unmet medical needs. We strongly support establishing a framework for incorporating patient views into the development and regulatory review processes in a more structured and transparent way, both with respect to patient input for benefit-risk assessments and use of patient experience data in regulatory decision-making.

BIO is also pleased about the focus on precision medicine through genomics and regulatory science. Industrial scale biomarker qualification and full genome sequencing will help us better understand the molecular basis of disease and develop precision therapies tailored to each patient.

Furthermore, we support enhancing the FDA's scientific capacity by improving access to adequate funding, enhancing the ability to recruit and retain world-class scientific and technical experts, and expanding management processes and human resource functions to meet the complexities of 21st Century scientific discovery. We especially note the important inclusion in this legislation of provisions to ensure privately-paid user fees to FDA are protected from the effects of any future sequestration.

Chairman Upton, Congresswoman DeGette, Ranking Member Pallone, and all members of the Energy and Commerce Committee have worked tirelessly to help expedite the delivery of the next generation of modern medicines that will save lives and reduce and eliminate suffering. We look forward to the passage of H.R. 6 and continuing to work with the Senate to ensure that patients have access to new treatments and cures.

Sincerely,



James C. Greenwood
President & CEO